

K062704

**510K SUMMARY**

JUN - 8 2007

This summary of 510K safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

The assigned 510K number is:

1. Submitter's Identification:

Winner Industries Co., LTD & Winner Medical USA, Inc.  
Winner Industrial Park, Bulong  
RD., Longhua, Shenzhen  
Shenzhen China 518109  
Telephone: 86-755-28138888  
Facsimile: 86-755-28134588

U.S. Agent for Winner Industries Co., LTD:  
Winner Medical USA, Inc.  
1037 Walnut Ave.  
Pomona, California 91766  
Telephone: 909-465-0598  
Facsimile: 909-465-0729

Contact Person: Ming Xie, Vice President

Date of Summary: 9-4-06

2. Device Name: Sterilization Pouch with indicators
3. Classification Name: Pack, Sterilization Wrapper, Bag and Accessories (21 CFR 880.6850).
4. Predicate Device:
- a. K051242 - Winner® Self Seal Sterilization Pouch.
  - b. K993764 - Medipack® See-Through Self Seal Sterilization Pouch.
  - c. K990567 - Global Healthcare Self-Sealing Sterilization Pouch.

5. Intended Use: Sterilization Pouch with indicators is intended to be used to enclose another medical device that is to be sterilized by a health provider by steam 121°C for 15 minutes or ethylene oxide (EtO). It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used.
6. Device Description/ Comparison: These pouches are manufactured from a medical grade paper and plastic film that are heat sealed on three sides. The fourth side has an adhesive strip that is used to seal the pouch. The medical grade paper conforms to recognized material standards and can be sterilized by steam or ethylene oxide gas. The Sterilization Pouch with indicators has the identical intended use, components, and manufacturing methods as our previous Self Seal Sterilization Pouch. Substantial equivalent to the predicate device was established by physical testing of the medical grade paper (pressure drop vs. flow and filtration efficiency) and film (thickness, tensile strength and elongation) from non-sterile, steam sterilized and ethylene oxide sterilized finished devices, as well as, performance of these finished devices (seal strength, package burst, dye migration, temperature distribution for steam and ethylene oxide sterilization, steam and ethylene oxide sterilization of biological indicators). The process indicators meet the performance requirements of ANSI/AAMI ST60:1996 standard entitled "Sterilization of health care products - Chemical indicators – Part 1: General requirements".



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

JUN - 8 2007

Winner Industries Company, Limited  
C/O Ming Xie, Ph.D.  
Vice President  
Winner Medical (USA), Incorporated  
1037 Walnut Avenue  
Pomona, California 91766

Re: K062704

Trade/Device Name: Winner® Self Seal Sterilization Pouch with Steam and  
Ethylene Oxide Process Indicators

Regulation Number: 21 CFR 880.6850

Regulation Name: Sterilization Wrap

Regulatory Class: II

Product Code: FRG

Dated: May 15, 2007

Received: May 17, 2007

Dear Dr. Xie:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K062704

Device Name: Winner® Self Seal Sterilization Pouch with Steam and Ethylene Oxide Process Indicators

Indications For Use:

Winner® Self Seal Sterilization Pouch with Steam and Ethylene Oxide Process Indicators is intended to be used to enclose another medical device that is to be sterilized by a health provider by steam 121°C for 15 minutes or greater than or equal to 600 mg/l of ethylene oxide (EtO) for 1 hour at 55° C and 70%RH. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The process indicators on the pouches are intended to demonstrate that the device has been exposed to the steam or EtO sterilization process and to distinguish between processed and unprocessed devices.

Prescription Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)

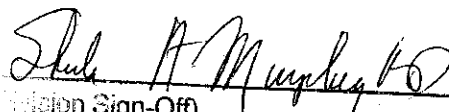
AND/OR

Over-The-Counter Use X  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OVD)

  
(Signature Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number: K 062 704

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